

773-60

08/26/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

8-26-13

Micah Reynolds
TSG Inc
1150 18th Street NW, Suite 1000
Washington, DC 20036

Subject: Amended Reregistration Label
Product Name: Atroban 42.5%EC
EPA Registration Number: 773-60

Dear Mr. Reynolds:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the permethrin RED(s), and has concluded that your submission is acceptable.

NOTE: This product is not being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label or durably marked on the container itself, and can be added by non-notification per PRN 98-10.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF and Alternate CSFs #1-4 dated 10-16-12

A copy of your label stamped "Accepted" is enclosed for the subject product. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions about this letter, please contact either Erik Kraft at (703-308-9358) or via email at Kraft.Erik@epa.gov or Richard J. Gebken at (703) 305-6701 or via e-mail at Gebken.Richard@epa.gov.

Sincerely yours,



Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

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(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

(MASTER LABEL)

RESTRICTED USE PESTICIDE

*Due to Dermal Irritation.

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

ATROBAN® 42.5% EC

(Alternate Brand Names: ATROBAN® 42.5% EC Insecticidal Spray)

Emulsifiable Concentrate Insecticidal Spray For Livestock and their premises

ACTIVE INGREDIENT:

Permethrin: 3-(phenoxyphenyl)methyl (±) cis, trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate*42.5%

OTHER INGREDIENTS57.5%
100.0%

*cis/trans ratio: Max. 55% (±) cis and min 45% (±) trans

This product contains xylene. Contains petroleum distillates.

This product contains 0.45 lbs (204 g) of permethrin per pint (473 mL)

ACCEPTED
8-26-13
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 773-60

DANGER KEEP OUT OF REACH OF CHILDREN

See [back] [other] [side] [panel] for additional precautionary statements.

[See booklet for First Aid and Directions for Use]

[Manufactured [by]][[for]:]

Intervet, Inc. (d/b/a Merck Animal Health)

556 Morris Avenue

Summit, NJ 07901

EPA Reg. No. 773-60

EPA Est. No. [6175-LA-1]

Net Contents: [One U.S. Pint (473 mL)]

[UPC Code]

[Copyright XXXX]

[All rights reserved.]

[Rev. XXX]

[Lot/Batch No.] (Note to reviewer: the lot or batch number may also be stamped directly on the product container.)

[Pull here to open] [Press to reseal]

ATROBAN® 42.5% EC; EPA Reg. No. 773-60

MASTER LABEL – dated August 15, 2013

Permethrin Re-Registration

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(Note to Reviewer: [bracketed text] is optional or alternate wording; (parenthetical text) is informational.)

| FIRST AID | |
|---|---|
| IF ON SKIN OR CLOTHING | Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. |
| IF IN EYES | Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. |
| IF SWALLOWED | Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person. |
| IF INHALED | Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice. |
| HOTLINE NUMBER | |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific Time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222. | |
| Note to Physician: Contains petroleum distillates. Vomiting may cause aspiration pneumonia. | |

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: DANGER: Corrosive. Causes skin burns. Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Mixers, loaders, applicators, and other handlers must wear: Protective eyewear, Coveralls over long-sleeve shirt and long pants, chemical-resistant footwear plus socks, chemical-resistant gloves for all handlers, chemical-resistant apron for mixers/loaders, persons cleaning equipment, and persons exposed to the concentrate.

USER SAFETY REQUIREMENTS

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

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USER SAFETY RECOMMENDATIONS

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. User should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. To protect the environment do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters, or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems.

This pesticide is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

PHYSICAL AND CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.

**DIRECTIONS FOR USE
RESTRICTED USE PESTICIDE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS

Except when applying to livestock:

- Do not apply this product in a way that will contact adults, children, or pets, either directly or through drift.
- Only protected handlers may be in the area during application.
- Do not enter or allow or allow others to enter treated area until sprays have dried.
- Do not enter or allow other to enter treated area until vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated.

Do not breathe vapors or spray mist.

When used in dairy barns or facilities: Close milk bulk tank lids to prevent contamination from spray and from dead or falling insects. Remove or cover milking utensils before application. Wash teats of treated animals before milking.

Not for use in outdoor residential misting systems (indoor or outdoor).

Dip Treatment Instructions: Charge dip vats with recommended application concentration by using quantities of ATROBAN® 42.5% EC and clean water as directed below. Mix thoroughly before each use. Dip to thoroughly wet animals to ensure complete coverage.

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Spray Treatment Instructions: For all sprays intended for direct application to animals and building surfaces, add ATROBAN® 42.5% EC to clean water as directed below, mix thoroughly and apply as a coarse spray. Spray lactating dairy cows *only* after milking is completed.

APPLICATIONS

The use of ATROBAN® 42.5% EC requires no withdrawal period between last application and slaughter.

For Control of Horn Flies on Beef, Dairy Cattle (Lactating and Non-Lactating), and Horses: Dilute ATROBAN® 42.5% EC with clean water at a ratio of 1:1600 (1/2 pint/100 gal). A 1:1600 dilution gives a 0.027% permethrin concentration. Apply sufficient spray (approximately 1 qt/animal) or dip to thoroughly wet animals to ensure complete coverage. Repeat applications as needed but not more often than once every 2 weeks.

For Control of Horn flies, Face flies, Stable flies, House flies, Horse flies, Mosquitoes, and Lice on Beef, Dairy cattle (Lactating and Non-Lactating), Sheep, Goats and Horses: Dilute ATROBAN® 42.5% EC with clean water at a ratio of 1:800 (1 pint/100 gal). A 1:800 dilution gives a 0.054% permethrin concentration. Apply sufficient spray (approximately 2qts/animal) or dip to thoroughly wet animals to ensure complete coverage. Repeat applications as needed but not more often than once every 2 weeks.

For Control of Ticks (including the genera *Boophilus* spp., *Amblyomma*, *Dermacentor*, and *Rhipicephalus*), Chorioptic mites, and Psoroptic (Scabies) mites on Beef, Dairy Cattle (Lactating and Non-Lactating), Sheep, Goats, and Horses: Dilute ATROBAN® 42.5% EC with clean water at a ratio of 1:800 (1 pint/100 gal). A 1:800 dilution gives a 0.054% concentration. Apply sufficient spray (approximately 2 qts/animal) or dip to thoroughly wet animals to ensure complete coverage. Repeat applications as needed but not more often than once every 10 to 14 days.

For Control of Northern fowl mites and Lice on Poultry in Cages or Houses: Dilute ATROBAN® 42.5% EC with clean water at a ratio of 1:800 (1/4 pint/25 gal). A 1:800 dilution gives a 0.054% permethrin concentration. Apply sufficient spray (approximately 1 gal/100 birds). One application should control an infestation. Do not treat more often than once every 2 weeks and do not apply more than four treatments.

For Control of Hog lice on Swine: Dilute ATROBAN® 42.5% EC with clean water at a ratio of 1:800 (1/4 pint/25 gal). A 1:800 dilution gives a 0.054% permethrin concentration. Apply sufficient spray to thoroughly wet animals to ensure complete coverage (approximately 1 pint/animal). One application should control an infestation. Do not treat swine 5 days prior to slaughter.

For Control of Mange mites on Swine: Dilute ATROBAN® 42.5% EC with clean water at a ratio of 1:400 (1/4 pint/12½ gal). A 1:400 dilution gives a 0.108% permethrin concentration. Apply sufficient spray to thoroughly wet animals to ensure complete

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coverage (approximately 1 pint/animal). Repeat application in 14 days. Do not treat swine 5 days prior to slaughter.

For use in and around Horse, Beef, Dairy, Swine, Sheep, and Poultry Premises and Outside Meat Processing Premises for Control of House flies, Stable flies, and Little House flies (*Fannia* spp.). NOTE: This product is not recommended for use on vinyl or plastic surfaces. Dilute ATROBAN® 42.5% EC with clean water at a ratio of 1:320 (1/4 pint/10 gal). A 1:320 dilution gives a 0.128% permethrin concentration. For small amounts of finished spray, mix 1½ teaspoonfuls in a gallon of water. Apply finished spray to surfaces where flies rest at the rate of one gallon per 750-1000 sq ft, but do not allow runoff to occur. Timing and frequency of application should be based upon flies reaching nuisance levels, but not more often than once every 2 weeks. If, under conditions of heavy fly pressure, longer residual control is desired, it is permissible to double the above concentration for premise application. Do not apply dilution for premise treatment directly on livestock or poultry. Ensure that animals' feed and water are not contaminated by spray drift. Do not use in milk rooms.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: Store in cool, dry place.

PESTICIDE DISPOSAL: Pesticides wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

[Optional Warranty Statement

NOTICE OF WARRANTY

To the extent consistent with applicable law, Intervet, Inc./Merck Animal Health makes no warranty of merchantability, fitness for any particular purpose or otherwise, expressed or implied, concerning this product or its uses which extend beyond the use of the product under normal conditions in accord with the statements made on this label.]

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Optional Marketing claims, pictograms, and product information
(May be presented on the container or supplemental labeling)

- Insecticidal Spray
- Made in the USA
- Merck Animal Health and/or Intervet Logo
- Treats 800 550 lb Head of Cattle based on horn fly dosage
- Pictures of Application Methods, Use Sites, and Target Pests
- Spray, Premises icons